NIMH
National Institute of Mental Health

NATIONAL INSTITUTE OF MENTAL HEALTH, NIH, DHHS
REQUEST FOR PROPOSAL - SOLICITATION COVER PAGE

REQUEST FOR PROPOSAL NO:	**NIMH-03-DB-0004**
TITLE:	**"NIMH Psychoactive Drug Screening Program"**
OMB No.: 0990-0115	**PURCHASE AUTHORITY:** Public Law 92-218 as amended; Note: The issuance of this solicitation does not commit the Government to make an award, or to pay any costs for the preparation and submission of a proposal.
ISSUED BY: Bruce E. Anderson Contracting Officer Contracts Management Branch National Institute of Mental Health, NIH, DHHS Neuroscience Center Building, 8155 (MSC 9661) 6001 Executive Blvd. Bethesda, MD 20892-9661 **POINTS OF CONTACT:** Bruce E. Anderson, Contracting Officer E-mail: ba9i@nih.gov Phone (301) 443-2696 or 2234 Fax at (301) 443-0501 Collect calls will not be accepted. Alex Navas, Contract Specialist E-mail: anavas@mail.nih.gov (301) 443-2696 or 2234 Fax Same as Above Collect calls will not be accepted.	**ISSUE DATE:** April 21, 2003 **DUE DATE: June 6, 2003** **4:30 p.m., local prevailing time** **Note:** The official Point of Receipt for the purposes of determining timely delivery is the Contract Management Branch, NIMH. A paper copy with original signatures is the official copy for recording timely receipt. If the Contracting Officer or Designee does not receive your proposal at the place and time specified, then it will be considered late and handled in accordance with PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this solicitation. Facsimile submissions are not acceptable.
NO. OF AWARDS: **PERIOD OF PERFORMANCE:**	**One (1)** **Three (3) years, beginning on or about September 30, 2003, with two (2) one-year options to extend (total 5 years)**
SMALL BUSINESS/ 8(a) SET-ASIDE:	**No - NAICS Code 541710** **Size Standard: 500 employees**
JUST IN TIME:	**Yes**
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Attachment 4)
TECHNICAL PROPOSAL PAGE LIMITS: **AWARD WITHOUT DISCUSSIONS:**	**No** The Government anticipates making an award after conducting negotiations, but reserves the right to make an award without discussions

NOTE: OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE NIMH WEBSITE AT http://www.nimh.nih.gov/grants/indexcon.cfm or http://www.fedbizopps.gov FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. THIS OFFICE WILL PROVIDE NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

April 21, 2003

Dear Sir/Madam:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-03-DB-0004 entitled **"*NIMH Psychoactive Drug Screening Program.*"**

The documents included with this electronic RFP package are as follows:

Streamlined RFP:
Part I

- Statement of Work (SOW) **(Attachment 1)**
- Evaluation Factors for Award **(Attachment 2)**

Part II Section l – Instructions, Conditions, and Notices to Offerors **(Attachment 3)**
Part III

- Applicable RFP References/Forms/Web links **(Attachment 4)**
- Proposal Intent Response Sheet **(Attachment 4)**
- Customer Past Performance Questionnaire **(Attachment 5)**

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition. Special attention should be directed to the technical and business proposal instructions contained in **Attachment 3. Also, attachment 5** must be sent to all previous/current customers, which are provided in the business proposal as references to support a past performance review by the Government

It is required that your organization submits both a technical proposal (detailing the methods and qualifications to do the work), and a business proposal (detailing the estimated prices and costs).

An official authorized to contractually bind your organization must sign the proposal. One (1) original and ten (10) copies of your technical proposal, and one (1) original and five (5) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN **4:30 p.m.**, **local prevailing time, on Friday, June 6, 2003**, at the following address:

If using overnight delivery service	**If using U.S. Postal Service**
Attn: Bruce E. Anderson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 8155 (MSC 9661) Rockville, MD **20852**-9661	Attn: Bruce E. Anderson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 8155 (MSC 9661) Bethesda, MD **20892**-9661

Your attention is further directed to the "Proposal Intent Response Sheet" at the end of **Attachment 4**. Please complete this form and return it to this office or notify me at ba9i@nih.gov on or before May 6, 2003, if are planning to submit a proposal. This will allow us to expedite preparations for the peer review of proposals.

Cover Letter
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Questions concerning any areas of uncertainty, which in your opinion require clarification or correction, must be furnished in writing (Fax or E-mail is acceptable) to Bruce E. Anderson, and marked "Offeror's Questions, RFP No. NIMH-03-DB-0004".

Sincerely,

/s/

Bruce E. Anderson
Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

Table of Contents/Attachments

PART I

ATTACHMENT 1
April 21, 2003
[Return to TOC]

STATEMENT OF WORK

TITLE: NIMH PSYCHOACTIVE DRUG SCREENING PROGRAM

I. Background:

The mission of the Molecular and Cellular Neuroscience Research Branch (MCNRB) is to support fundamental research on the mechanisms underlying and influencing brain development, neuronal signaling, synaptic plasticity, signal transduction pathways, and the biochemical and behavioral actions of therapeutic agents in animals and humans. The goals of the MCNRB include the identification of novel targets (genes or molecules) for therapeutic intervention, characterization of the behavioral actions of psychoactive agents, and design and development of novel ligands for functional brain imaging in humans, psychoactive agents for basic and clinical research, and potential therapeutic agents for the treatment of mental disorders.

To further these goals, a contract for the NIMH Psychoactive Drug Screening Program (PDSP) was initiated in 1992 and awarded again in 1998 to provide broad-based screening capabilities, in the form of pharmacological and functional assays, and receptor binding data (Ki values) to the scientific research community with the intent of stimulating innovative research and development efforts in the design and development of novel psychoactive compounds for preclinical research, neuroimaging, and as potential therapeutic agents in the treatment of psychiatric disorders. The program focuses on the use of state-of-the-art, high-throughput screening of compounds in human and rodent CNS receptor and enzyme assays and biochemical assays to assess functional activity.

Objectives:
The purpose of the NIMH Psychoactive Drug Screening Program is to provide pharmacological and functional screening of novel synthetic compounds and natural products for potential use as PET, SPECT, and fMRI ligands for functional brain imaging, research tools or probes for basic and clinical research, and therapeutic agents for mental disorders. This screen is not intended for the purpose of large-scale, random screening of natural products or combinatorial libraries but as a screen for compounds that have previously been shown to possess pharmacological, biochemical, or behavioral activities relevant to NIMH.

The objectives of the contract are to receive and test approximately 1,000 (but could range from 500-1,500) coded samples (synthetic compounds, small molecules, gene products, and natural product extracts) per year, as specified by the GPO, in broad-based human and rodent CNS receptor and enzyme screening assays, to test active samples in secondary functional assays, and to provide an electronic data file for each of the screened compounds. Approximately 80% of these samples are to be tested in human recombinant receptor assays. Samples for screening can include, but are not limited to, novel chemical entities, structural analogs of lead compounds, genes or gene products, small molecules, enzyme inhibitors, and natural products. It is anticipated that NIMH-approved and coded samples will be submitted from NIH-funded research programs, academic research programs, or other sources. It is expected that the screening information derived from this program will provide individual investigators with conceptual or structural leads for the design and/or development of new chemical entities, small molecules, gene products, tissue- or cell-specific drug delivery systems, therapeutic entities, or PET, SPECT, and fMRI ligands for human brain imaging.

II. SERVICES TO BE PERFORMED:

A. General Requirements

Independently, and not as an agent of the federal government, the contractor shall furnish all necessary labor (qualified and experienced personnel), services, equipment, materials, supplies, and facilities, except as otherwise specified herein, as needed to perform the work set forth below. All work under this contract shall be monitored by the Government Project Officer (GPO) whose position is defined in Section G of this contract.

B. Specific Technical Requirements

The contractor shall use Good Laboratory Practices (GLP) to conduct all aspects of the contract, as specified in the tasks listed below.

Outline/Overview of the Sample Screening Process

a. Investigator contacts Contractor or GPO about submitting samples to NIMH screening program
b. Investigator obtains sample assay form and assay checklist from NIMH or Contractor web pages
c. Investigator forwards sample assay form to Contractor
d. Contractor appraises sample assay request and forwards to GPO within 1 week of receipt
e. GPO approves, amends, or denies sample assay request based on Contractor's appraisal and on NIMH programmatic considerations within 2 business days of receipt
f. Contractor sends sample vials to investigator within 3 business days of GPO approval of sample assay request
g. Investigator returns samples to Contractor at own expense and provides sample information and handling instructions
h. Sample(s) received by Contractor, stored according to specifications, and scheduled for assays which it is anticipated will be completed within 2-3 weeks of receipt of samples
i. Pharmacological assays performed in duplicate at sample concentration of 10 μM or less as requested by investigator (50 μg/ml or less for natural products)
j. Sample inhibits specific binding less than 75%: no further testing; assay report sent to investigator
k. Sample inhibits binding by at least 75%; Contractor shall obtain GPO approval for further testing
l. Quantitative analysis of sample binding affinity performed in duplicate with 6-8 concentrations (at least 4 concentrations yield > 20% and < 80% specific binding)
m. Data analysis and sample assay report generated and sent to GPO for review and approval within 1 week of completion of screening and/or data analysis
n. GPO reviews assay report and responds to Contractor within 2 business days; if approval is given, report sent to investigator within 2 days of approval; if report is not approved, GPO will discuss with Contractor to resolve any concerns
o. Sample(s) approved for functional assays and scheduled for assays within 2-3 weeks of receipt of samples
p. Functional assays performed in duplicate at K_i value with 2 lower and 2 higher concentrations
q. Data analysis and sample assay report generated and sent to GPO for review and approval within 1 week of completion of screening and/or data analysis
r. GPO reviews assay report and responds to Contractor within 48 hours; if approval is given, report sent to investigator; if report is not approved, GPO will discuss with Contractor to resolve any concerns

Task 1. Establishment, Validation, and Quality Control of Pharmacological and Functional Assays

a. The Contractor shall submit, within 2 calendar weeks of contract award, an Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approval to ensure compliance with the NIH guidelines. The Contractor shall apply to the Office for Protection From Research Risks (OPRR) at the National Institutes of Health (NIH) for a project assurance number, if such a number has not been assigned to the Contractor by OPRR. By obtaining a project assurance, the Contractor agrees to maintain compliance with the NIH guidelines for care and use of vertebrate animals and the handling of human tissue.

b. The Contractor shall submit, within 2 calendar weeks of contract award, a detailed protocol for quality control measures to ensure high-quality work and reliability of pharmacological and functional assays, to ensure that all samples and reference standards are handled and stored according to specifications, to ensure that all samples and reference standards remain free of contamination by bacteria or other agents, and to prevent sample mix-ups. The GPO shall review the final protocol, which shall be in place within four calendar weeks after the contract award.

c. The Contractor shall submit, within 2 calendar weeks of contract award, a detailed data management protocol that addresses the requirements of Task 7.

d. The Contractor shall submit, within 2 calendar weeks of contract award, a detailed protocol, timetable, and estimated labor required to establish and validate each additional cloned human and rodent receptor binding, enzyme, or functional assay to be included in the NIMH Screening Assays, as requested by the GPO.

e. The Contractor shall obtain and maintain stably transfected cell lines expressing a specified receptor (as requested by the GPO and according to the timetable in Task 1d) and evaluate standard reference compounds in state-of-the-art radioligand binding assays). Assay characteristics (i.e., K_D (binding affinity), B_{max} (receptor number), degree of specific binding, receptor source, radioligand, reference compounds, and incubation conditions) shall be in accordance with the current standards established in the published scientific literature. The assays shall be reviewed and approved by the GPO prior to inclusion in the NIMH Screening Program.

Task 2. Pharmacological Screening: Radioligand Binding and Enzyme Assays

a. The Contractor shall provide state-of-the-art, high-throughput screening to evaluate approximately 1,000 (but could range from 500-1,500) coded compounds per year (synthetic compounds, gene products, and natural product extracts), as specified by the GPO, in broad-based pharmacological assays (radioligand binding and enzyme assays).

b. Pharmacological screening capabilities shall consist of state-of-the-art radioligand binding assays using cloned human and rodent CNS receptors. Receptor assays shall include, but are not limited to, serotonin, dopamine, glutamate, GABA, adrenergic, opioid, muscarinic, and histamine receptor subtypes, ion channels, transporters, neuropeptide receptors, second messengers, and enzyme assays (phosphodiesterase types, tyrosine hydroxylase, tryptophan hydroxylase) as specified in the attached list of assays of interest to NIMH **(see Appendix 1)**.

c. Primary Pharmacological Assays. The Contractor shall screen each sample in one or more assays, as requested by the investigator and authorized by the GPO. It is anticipated that approximately 5,000 (but could range from 4,000-6,000) sample assays may be requested per year (based on an approximation of

10 assays per sample). Samples shall be evaluated in duplicate in each assay at a single concentration of 10 μM or less for synthetic compounds and 50 μg/ml or less for natural products as recommended by the investigator. A standard reference compound or compounds shall be run simultaneously with each sample or batch of samples tested in a given assay (e.g., in a 96 well plate or equivalent format).

d. Secondary Pharamacological Assays. Quantitative analysis of binding affinity will be determined for each sample that produces at least 75% inhibition of specific binding in a given receptor or enzyme assay. A competition curve for the sample shall be generated in duplicate consisting of six to eight concentrations, with at least four sample concentrations yielding greater than 20% and less than 80% inhibition of specific binding. A standard reference compound shall be simultaneously run for each assay performed on a sample or batch of samples. It is anticipated that approximately 30% (but could range from 15-45%) of samples screened in pharmacological assays (Task 2c) will produce at least 75% inhibition of binding in a given assay and will be approved for further testing to determine binding affinity (Task 2d). Based on this anticipated rate, the Contractor shall provide approximately 800 (but could range from 500-1,000) secondary pharmacological assays per year. The anticipated time frame for completion of the quantitative analysis of sample binding affinity is one to two weeks after completion of screening in Task 2c.

e. Competition curves for samples and reference compounds shall be analyzed by non-linear regression using computerized curve-fitting programs such as LIGAND, InPlot, Sigmaplot, or EBDA to determine estimates for IC_{50} values (50% effective concentration) and Hill coefficients (n_H).

f. The Contractor shall provide a graph containing the individual competition curves obtained for each sample in a given assay and the competition curve(s) for the standard reference compound(s) plotted as log drug concentration on the abscissa and % specific binding on the ordinate. Data shall be summarized in terms of an IC_{50}, K_i (equilibrium dissociation constant), n_H, and standard ratio (K_i of reference compound to K_i of test compound). Mean $\pm$ SEM, mean and confidence limits, or mean and range shall be determined for each of the values.

g. The anticipated time frame for completion of sample screening and data analysis is 2 - 3 weeks after receipt of the sample. Sample assay reports shall be prepared and sent to the GPO (electronically or by fax) for review and approval prior to release of the data to the requesting investigator (**see Task 9**).

h. For the purpose of quantifying work, each type of receptor binding assay in which a sample is evaluated shall be defined as one (1) Task 2 sample assay.

Task 3. Functional Screening: Cellular Assays

a. Functional Assays. The Contractor shall provide approximately 525 (but could range from 300-700) functional assays per year to determine the *in vitro* agonist, partial agonist, or antagonist properties of samples as specified by the GPO. Cellular assays shall include, but are not limited to, uptake assays for transporters (norepinephrine, serotonin, dopamine), measurement of G-protein coupling (e.g., GTPγS binding or other assays), and measurement of second messengers (e.g., adenylyl cyclase, cyclic AMP, phosphatidylinositol hydrolysis, and arachidonic acid). Samples shall be tested in duplicate at six concentrations in functional assays for human or rodent receptors.

b. The specific types of receptor assays in which a sample is evaluated shall be dependent on the binding affinity (e.g., a K_i value of 1 μM or less) and the approval of the GPO. Samples shall be tested in duplicate at the K_i value with 2 lower and 2 higher concentrations. For each assay, the type of tissue

preparation used and the assay conditions shall be subject to approval of the GPO. The dose-response curve shall be repeated, if necessary, at the request of the GPO.

c. The Contractor shall provide a graph containing the individual dose-response curves obtained for each sample in a given assay and the standard reference compound(s) plotted as log drug concentration on the abscissa and % activity on the ordinate. Data shall be summarized in terms of an EC_{50}, IC_{50}, K_i, K_M, V_{max}, and/or pA_2 values dependent upon the type of assay conducted. Mean $\pm$ SEM or mean and confidence limits shall be determined from each value.

d. The anticipated time frame for completion of sample screening and data analysis is 2-3 weeks after receipt of the sample. Sample assay reports shall be prepared and sent to the GPO (electronically or by fax) for review and approval prior to release of the data to the requesting investigator (see Task 9).

e. For the purpose of quantifying work, each type of functional assay in which a sample is evaluated shall be defined as one (1) Task 3 sample assay.

Task 4. Assays to Assess Brain Penetrance, Bioavailability, and Cardiac Toxicity

The Contractor shall provide state-of-the-art, high-throughput screening to evaluate a subset of coded compounds per year (approximately 100 compounds, but could range from 75-200) as specified by the GPO, in one or more of the following assays:

a. Bioavailability: Caco-2 cell assays to ascertain absorption and/or secretion of drugs/chemicals across the intestinal mucosa

b. Model assays for blood brain barrier penetration (including efflux pumps, transporters and tight junctions). Efflux pump assays could include P-glycoprotein (P-gp) subtypes and multidrug resistance-associated proteins (MRPs).

c. Plasma protein specific binding: albumin binding (specific binding, e.g., warfarin binding site)

d. Predictive measures of Log P - hydrophobicity/lipophilicity

e. Model assays to predict cardiac toxicity such as prolongation of the Q-T interval or human valvular interstitial cell assay

f. QSAR/QSPR (quantitative structure activity or property relationships) modeling programs to predict log P, ADME (Absorption, Distribution, Metabolism, Excretion), and toxicity

Task 5. Development and Validation of New Assays

a. The Contractor shall maintain a state-of-the-art knowledge of the field in order to update existing assays, establish binding assays for newly cloned human or rodent receptors and enzymes including orphan receptors, and establish new functional assays. For example, the Contractor shall have the capabilities to clone a newly discovered CNS receptor, maintain a stably transfected cell line expressing the receptor, and establish the binding and functional assays for the receptor in accordance with the standards established in the published scientific literature (i.e., K_D, B_{max}, degree of specific binding, radioligand, reference compounds, incubation conditions, etc.). It is anticipated that the Contractor will develop approximately 5-10 new assays per year. This task can include the development of non-radioactive ligand binding technologies such as fluorescent-based assays.

b. The Contractor shall provide the GPO with a timetable and estimate of the labor required to develop and validate each new pharmacological or functional assay prior to undertaking the work. The Contractor shall provide an update on the status of the assay (progress, obstacles encountered) in the monthly reports.
c. The assays shall be reviewed and approved by the GPO prior to inclusion in the NIMH Screening Program.

c. As necessary, the GPO may ask the Contractor to perform radioligand-binding assays using cell membrane preparations obtained from fresh tissues of human or rodent origin instead of stably transfected cells.

Task 6. Processing Sample Requests, Approval for Evaluation, Receipt, Storage, and Confidentiality

a. The Contractor shall review sample assay requests from investigators and make recommendations for screening in the requested assays within one week of receipt of screening information. The GPO shall approve and prioritize all sample screening requests based on the Contractor's appraisal and on NIMH programmatic considerations.

b. After a sample has been approved for screening by the GPO, the Contractor shall package and ship coded sample vials, sample information sheets, and assay checklist to the investigator via overnight express delivery. Shipment of sample vials to investigators shall be paid by the Contractor and charged to the contract. Investigators shall be responsible for paying the costs of returning the coded sample vials containing the appropriate amount of sample to be tested, sample information sheets, and assay check list via overnight express delivery to the Contractor in a timely manner.

c. The Contractor shall maintain an electronic chronological log of sample receipt, handling, and storage conditions in the Microsoft Excel for PCs (the most recent version released or that has been released within the 18 months prior to the date of contract award). When a sample is received, the following entries shall be made: 1) sample identification number or name; 2) source of compound (investigator name affiliation, phone, fax, and e-mail); 3) date of receipt; 4) sample storage information such as stability, light sensitivity, temperature, nitrogen gas, etc.; 5) sample handling requirements such as solubility, preferred solvent, and stability in solution

d. The Contractor shall store samples as specified by the investigator. Samples shall be weighed out not more than one working day prior to evaluation.

e. All proprietary and non-proprietary samples or compositions of matter submitted for testing under this contract shall be disposed of by the Contractor within 60 days after the sample assays, data analyses, and sample assay reports have been completed and approved by the GPO.

Confidentiality

f. The Contractor shall protect the confidentiality, intellectual property and patent rights to any proprietary sample or composition of matter submitted for testing, including data, product designs, or inventions developed under this contract. The Contractor shall not use samples supplied by investigators under this contract for non-contract related research. The Contractor shall be prohibited from publishing or patenting any uses, product designs, or inventions resulting from samples submitted for testing under the contract. The Contractor shall not publish any data generated from any coded, proprietary or non-proprietary sample submitted for testing under the contract, without written approval of the GPO and Contracting Officer.

g. A deviation to the standard Patent Rights clause in FAR 52.227-14 will be used to ensure the confidentiality and protect the intellectual property and patent rights of an investigator or party supplying a proprietary sample or composition of matter for testing under this contract (**see Appendix 5**).

h. The compound supplier may also request that the Contractor sign agreements like those in **Appendices 3-4**:

- Appendix 3 - Standard Agreement For Submitting Compounds For Testing (Sample)
- Appendix 4 - Confidentiality and Nondisclosure Agreement (Sample).

Contractor's rights

i. The Contractor shall assume the intellectual property and patent rights for any invention related to pharmacological or functional assays, data analysis methodologies, or data management systems developed or modified under the contract, but not for proprietary samples. The Contractor shall notify the GPO and Contracting Officer 30 days in advance of the submission of any inventions or publications resulting from work done under this contract.

Task 7. Data Management and PDSP Ki Database

a. Non-proprietary data (i.e., data derived from compositions of matter in the public domain) generated under the contract shall be disseminated to individual investigators upon written approval by the GPO. Non-proprietary data generated under the contract may be provided as a resource on WWW pages maintained by NIMH and by the Contractor , upon written approval by the GPO.

The Contractor shall create/maintain 3 electronic databases as follows:

b. The Contractor shall maintain a secure, cumulative "internal" electronic database(s) of samples, compositions of matters, and reference compounds screened in pharmacological and functional assays.

This database shall be maintained in Microsoft Excel for PCs (the most recent version released or that has been released within the 18 months prior to the date of contract award) or a comparable program that is compatible with NIMH systems. The database shall contain receptor binding, enzyme activity, and functional activity profiles of samples and reference compounds as specified by the GPO (e.g., IC_{50}, K_i, K_D, Hill coefficient, dose ratio, pA_2 values determined in Tasks 2-3).

The database shall be updated monthly. The data shall be disclosed only to the GPO and to the investigator or party supplying the sample or composition of matter.

c. The contractor shall maintain the program's Binding Affinity (Ki) Database, a searchable database of over 20,000 binding affinities obtained from the literature and screening results. The database, currently maintained with MySQL (open source) software on a Linux (Unix based) server using PHP (hypertext preprocessor) language, shall be maintained in the public domain and shall be accessible to queries through the contractor-designed and maintained website for the program (see Task 8). The contractor shall update the database on a regular basis with new data obtained from the literature and from screening results.

d. The contractor shall also maintain the program's Radiotracer Database, a centralized database of radiotracers with relevant information including pharmacology, pharmacokinetics, synthesis protocols, toxicology and safety data, dosimetry, other clinical data, IND (Investigational New Drug) information,

permission to cross-reference toxicology data in a drug master file if an IND exists, contact information for citing toxicology data, patent, research use, etc. The database, currently maintained with MySQL (open source) software on a Linux (Unix based) server using PHP (hypertext preprocessor) language, shall be maintained in the public domain and shall be accessible to queries through the contractor designed and maintained website for the program (see Task 8). The contractor shall update the database as needed with information submitted to the program by investigators and from screening results.

Task 8. Other Activities

WWW resources and advertising activities

a. The Contractor shall design and maintain pages on the WWW with the following information: a description of the NIMH Psychoactive Drug Screening Program, procedures for submitting samples for screening, a list of the available pharmacological and functional assays, and a sample assay request form, and a sample information and handling form. The WWW pages shall contain the searchable binding affinity (Ki) and radiotracer databases (see Task 7). The pages shall be updated as needed.

b. NIMH shall maintain pages at http://www.nimh.nih.gov/mc/index.cfm with a description of the program. The Contractor WWW pages shall be linked to the NIMH pages.

c. The Contractor shall make information available about the NIMH Psychoactive Drug Screening Program at scientific meetings (e.g., the Society for Neuroscience annual meeting).

Task 9. Reporting Requirements

a. Sample Assay Reports

(1). Sample assay reports shall be submitted to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs (the most recent versions released or that have been released within the 18 months prior to the period for which the report is submitted) or comparable programs that are compatible with NIMH systems, within one week of completion of testing.

(2). Each assay report shall include: the sample receipt date, investigator name and affiliation, sample information, tests requested and approved, batch number and dates on which tests were run, raw data from pharmacological assays (% inhibition in each assay, total and non-specific binding, data for reference compounds), analysis of sample binding affinity in each assays in which the % inhibition of binding exceeds 75% (data shall be in graphic format with calculated values and SEM); raw data from functional assays, analysis of sample data (data shall be in graphic format with calculated values and SEM).

(3). The pharmacological significance of the sample data and/or recommendations for further testing of the sample shall be included in the report.

(4). The report shall be reviewed, assured for quality control, approved, signed, and dated by the Contract Project Officer prior to submission to the GPO.

(5). The GPO shall review and approve sample data reports prior to release of the data to the requesting investigator.

(6). After approval by the GPO, the sample assay report shall be submitted to the investigator or party supplying the sample for testing, within 2 business days.

(7). In the event that quality control/assurance issues arise with sample or reference compound data in any of the assays performed under the NIMH contract, the Contractor shall cooperate fully with the GPO to resolve the issues, if necessary repeating sample assays in the specified tests at no additional costs to the contract. In the event that sample or reference compound quality control or assurance issues in a given assay can not be resolved between the Contractor and GPO, a scientific advisory group chosen by the GPO shall be asked to review the data and make recommendations to resolve the issues.

b. Weekly Reports

(1). Weekly reports shall be submitted to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs (the most recent version released or that has been released within the 18 months prior to the period for which the report is submitted) at the end of each week.

(2). The report shall include a summary of the number and type of samples received over the course of the week and the screening status of each sample.

(3). Clear documentation of unsuccessful efforts in sample screening in any pharmacological and functional assay and actions taken.

(4). Summary of any new assays developed and validated under the contract and the status of any assays in development.

c. Monthly Reports

(1). Monthly reports shall be submitted to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs (the most recent version released or that has been released within the 18 months prior to the period for which the report is submitted) or comparable programs that are compatible with NIMH systems, within 7 calendar days after the end of each contract month.

(2). The report shall include a summary of the number and type of samples (synthetic chemicals, natural products, PET/SPECT ligands, etc.) received over the course of the month, the screening status of each sample, and assay reports for each sample as specified above.

(3). Clear documentation of unsuccessful efforts in sample screening in any pharmacological or functional assay and actions taken.

(4). Summary of any new assays developed and validated under the contract.

(5). An update on the status of the PDSP Ki database and radiotracer database and web server statistics on the databases (e.g., the number of requests, amount of data transferred, etc).

(6). Copies of any scientific publications that result from screening data generated under the contract.

d. Annual Reports

(1). Annual reports shall be submitted to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs (the most recent versions released or that have been released within the 18 months prior to the period for which the report is submitted) or comparable programs that are compatible with NIMH systems, within 14 calendar days after the end of each contract year.

(2). The annual report shall be compiled to summarize the information contained in that year's monthly reports.

(3). The report shall include: 1) the cumulative chronological log of sample receipt, handling, and storage conditions and electronic database of investigators who have had samples screened under the contract, including each investigator's, affiliation, phone, fax, and e-mail address; and 2) the cumulative up-to-date electronic database of all samples and reference compounds screened in the pharmacological and functional assays.

(4). An update on the status of the PDSP Ki database and radiotracer database and web server statistics on the databases (e.g., the number of requests, amount of data transferred, etc).

e. Final Report

(1) The final report shall be submitted in addition to the annual report for the final year.

(2) The final report shall be submitted to the GPO electronically in Microsoft Excel or Microsoft Word format for PCs (the most recent versions released or that have been released within the 18 months prior to the period for which the report is submitted) or comparable programs that are compatible with NIMH systems, on or before the effective contract expiration date.

(3) The final report shall include an executive summary of all of the sample screening, assay development and validation activities conducted under the contract and an up-to-date protocol book of all pharmacological and functional assays available in the NIMH Psychoactive Drug Screening Program.

f. Transition Plan - Transition to a subsequent contractor

(1) At least 90 days prior to the contract expiration date, the Contractor shall provide a transition plan to the GPO with a list of all data programs and data files generated under the contract. At this time, the Contractor shall describe their plans for providing all such data and the up-to-date protocols for all pharmacological and functional assays used in the NIMH Psychoactive Drug Screening Program to a successor contractor or to NIMH.

(2) The Contractor shall fully cooperate with any successor contractor and NIMH to ensure the efficient transfer of all such data.

Task 10. Compound Library Screening **(Optional)**

a. Option for Increased Quantity (Mar 1989)

The Government may unilaterally direct the Contractor to screen a library of chemically diverse compounds in 40-100 CNS receptor-binding assays, at the costs estimated.

The Contracting Officer may exercise this option by giving written notice to the Contractor within 30 days prior to the required start of this effort, provided that written notice of intent to exercise this option was given at least 60 days prior to the start. Delivery of the added items shall be in conformance with the contract, unless the parties otherwise agree.

(End of clause)

b. The Contractor shall screen a library of chemically diverse compounds in 40-100 CNS receptor - binding assays and determine Ki values for any hits. Libraries of compounds could include the ChemBridge CNS-Set (50,000 compounds) developed to facilitate exploration of compounds likely to pass the blood brain barrier, a chemically diverse set of compounds assembled from the Tripos collection (50,000 compounds), a set of FDA approved drugs and purified natural products from Microsource, or componds from other sources. The chemical structure and pharmacological profile for compounds in the chemical library would be put into the public domain via the PDSP database or via an interface with an NIH database.

c. This task is an "option" for the Government, and may or may not be requested. If requested, this work will likely be performed in years 1-3. **(see C. Schedule of Work Requirements for Tasks 1 through 10, below, for more details)**

C. Schedule of Work Requirements for Tasks 1 through 10

1. Year One

a. Task 1: In months 1-3, the Contractor shall work mainly on establishing and validating additional pharmacological and functional assays, as requested by the GPO, to complete the NIMH list of pharmacological and functional screening assays.

The Contractor shall obtain and, if necessary, transfect cells with a specific receptor, maintain a stably transfected cell line, and evaluate 4-5 standard compounds for relative potency, kinetics, accuracy, and reproducibility in state-of-the-art radioligand binding assays. The resultant reference compound data shall be compared with data from peer-reviewed scientific articles. Assay data shall be reviewed and approved by the GPO prior to inclusion of the assay in the NIMH list of available pharmacological and functional assays.

b. Tasks 2-9: In months 4-12, the Contractor will begin receiving and processing samples/compounds, and updating/ maintaining the databases.

The annual assay workload (assays 2-5) is estimated as follows:

Task	Estimated No. of Sample Assays	Possible Range
2	5,800	4,500 -7,000
3	525	300 -700
4	200	
5	7 new assays developed and validated, as requested by the GPO	5-10

2. Years 2–5

During each subsequent year, including the option periods (if exercised), the Contractor shall do approximately the same type and volume of work as in year 1.

3. Optional Task 10 - Compound Library Screening

Listed below are the possible scenarios that may be requested under Task 10; if requested, they will likely be done in **years 1-3** of the contract.

Task 10 Scenario No.	No. of Compounds Screened	No. of Assays per Compound	Approximate Completion Time
1	50,000	40 assays	1 year
2	50, 000	40 assays	2 years
3	50,000	100 assays	2 years
4	50, 000	100 assays	3 years
5	100,000	40 assays	1 year
6	100,000	40 assays	2 years
7	100,000	100 assays	2 years
8	100,000	100 assays	3 years

D. Performance-Based Contracting (PBC)

The resulting contract will be performance-based (Performance Based Contract). The elements of a Performance Based Contract (PBC), included in the table below, are: 1) performance requirements/tasks; 2) performance/task standards; 3) method of surveillance/measurement techniques; 4) performance indicators; 5) positive and negative incentives/award fee structure. The method of surveillance also incorporates use of an award fee evaluation group. The award fee system is further explained in **Attachment 3**. If you are a commercial organization, you must propose a "base" fee and an "award" fee amount. If you are not a commercial organization, although a fee cannot be proposed, this contract will still be held to the standards below. Not-for-profit organizations (those which are allowed a fee), shall propose as a commercial organization. **See Attachment 3 for more information.**

[Note: The below table is subject to modification based on negotiations/discussions prior to award. Any modifications proposed by the offeror should be detailed in the original technical proposal. Only Tasks 2-4, 6, 8-9 will be subject to PBC]

PERFORMANCE STANDARDS AND MEASURES CHART

TASK	TASK STANDARD	METHOD OF SURVEILLANCE	PERFORMANCE INDICATORS	ASSIGNED WEIGHT
Task 2 Pharmacological Screening	Screening results are complete and are forwarded to investigators in a timely manner.	Investigators are contacted monthly to complete a customer evaluation of contractor performance.	Customers indicate satisfaction at least **80%** of the time.	
Task 3 Functional Screening	Screening results are complete and are forwarded to investigators in a timely manner.	Investigators are contacted monthly to complete a customer evaluation of contractor performance.	Customers indicate satisfaction at least **80%** of the time.	
Task 4 Assays to Assess Brain-Penetrance, Bioavailability, and Cardiac Toxicity	Screening results are complete and are forwarded to investigators in a timely manner.	Investigators are contacted monthly to complete a customer evaluation of contractor performance.	Customers indicate satisfaction at least **80%** of the time.	
Tasks 2,3,4 (i.e. All Screening)				**70% of the award fee amount**
Task 6 Processing of Sample Requests, Approvals for Evaluation, Receipt, Storage, and Confidentiality				
6a) Request Receipt and Review	Requests are reviewed by the contractor and forwarded to the GPO with recommendations for screening.	Responses to requests are reviewed for timeliness.	Requests are reviewed and the information sent electronically to the PO within **1 week** of the receipt of the request, at least **90%** of the time.	
6b) Sample vials	Coded sample vials, information sheets, and an assay checklist are shipped to investigators by the contractor in a timely fashion.	Investigators contacted at random to gain feedback on the timeliness of shipments	Shipments are made within **3 days** of approval by the GPO, at least **90% o**f the time.	
6c) Sample log	Contractor shall maintain a complete log of sample receipt, handling, and storage.	Log reviewed monthly as part of the monthly report.	Log contains entries for all compounds. Entries for each compound contain all the elements specified in the SOW.	
6d) Sample storage	Samples are stored according to the specifications of the requesting investigator.	Storage conditions reviewed monthly as part of the Sample Log (Task 6c)	Samples are stored and maintained according to investigator specifications.	
All Task 6				**10% of the award fee amount**

Task 8 Other Activities-WWW resources and Advertising	A contract website containing a description of the program, a list of assays available, and procedures for submitting requests is created and updated on a regular basis to incorporate changes	Website reviewed monthly to ensure that it is up to date.	Contract website is presented to the PO for approval within **2 weeks** of contract award date. Website is made live within **1 week** of receiving PO approval Website is updated within **5 days** of occurrence of a change, at least **90%** of the time.	**10% of the award fee amount**
	Information about the program is made available at appropriate scientific meetings Materials advertising this Program are to be developed for a particular meeting	PO will direct Contractor to travel to specific scientific meetings Review copies of literature provided to advertise the program. When possible, monitor advertising activities directly at the meeting	Contractor is available for at least two major scientific meetings per year to advertise the program Advertising materials (i.e, flyers, etc.) are completed in time for PO review before the meeting; content and layout is professional	
Task 9 Reporting Requirements	Complete weekly, monthly, and annual reports are received in a timely manner.	Review of reports	All reports contain all the elements specified in the SOW and/or by the PO, at least **90%** of the time. At least **90%** of the time, weekly reports are received within 3 calendar days of the end of each week, monthly reports within 7 calendar days of each contract month, and annual reports within 14 calendar days of each contract year	**10% of the award fee amount**

Summary of Award Fee

Task	**Total Award Fee**
Tasks 2,3, & 4	70%
Task 6	10%
Task 8	10%
Task 9	10%
	100%

E. Award Fee Ratings

An Award Fee Evaluation Group will evaluate the quality of the work provided using an adjectival rating scale with a corresponding percentage. The following reflects the rating factors and related definitions:

CPAF CONTRACT RATING TABLE

Definition of Rating	Specific Adjective Rating	Numerical Rating Column (100 percent possible) *
Superior - The Contractor's performance exceeds standard by substantial margin, and the monitor can cite few areas for improvement, all of which are minor.	Superior – award amount based on percentage earned	90-100%
Excellent - The Contractor's performance exceeds standard, and although there may be several areas for improvement, these are more than offset by better performance in other areas.	Excellent – award amount based on percentage earned	80-89%
Satisfactory - The Contractor's performance is standard and areas for improvement are approximately offset by better performance in other areas.	Satisfactory – award amount based on percentage earned	70-79%
Poor - The Contractor's performance is less than standard, and although there are areas of good or better performance, these are more than offset by lower rated performance in other areas.	Poor – earns no award fee	60-69%
Unacceptable - The Contractor's performance is less than standard by a substantial margin, and the monitor can cite many areas for improvement which are not offset by better performance in other areas. Less satisfactory performance would be unacceptable.	Unacceptable – reduces base fee by $_____	0-59%

*Whenever possible, the amount of award fee to be given to the Contractor will be an objective calculation of performance (i.e., the percentage attainment of a "standard" for a specific task(s) times the possible amount of award fee available; the computed amounts will be cumulated to recommend a total award fee earned for the period).

If the Contractor fails to meet the standard specified in the PERFORMANCE STANDARDS AND MEASURES CHART, no award fee will be given (i.e., a Poor/Unacceptable rating); if the Contractor exactly meets the standard, 70% award fee would be given (i.e., Satisfactory); performance above the standard will be a prorated mathematical computation; if the standard is met 100% of the time, the Contractor will always receive 100% of the award fee.

On some tasks it may not be possible, or practicable, to objectively measure performance; in these cases award fee calculations will be more subjective, based upon perception of the degree of professionalism and effort expended to achieve high standards.

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NIMH Pharmacological Assays of Interest[1] (see Task 2b)

Receptor Class	**Subtypes**
Serotonin	5-HT1A, 5-HT1B, 5-HT1Dα,β, 5-HT1E, 5-HT1F, 5-HT2A, 5-HT2B, 5-HT2C, 5-HT3, 5-HT4, 5-HT5A, 5-HT6, 5-HT7
Dopamine	D1, D2, D2L, D3, D4, D5
Glutamate	NMDA agonist site, glycine site, PCP site, AMPA, Kainate
Glutamate, metabotropic	mGluRs 1-8
GABA	GABA-A subtypes, GABA-B
Transporters	SERT, NET, DAT, glutamate (EAAC1), glycine (GLYT2), GABA (GAT-1, -3), VMAT-1, VMAT-2
Adrenergic	alpha1A, alpha2A, B, C, beta 1, 2, 3
Muscarinic	M1, M2, M3, M4, M5
Nicotinic	neuronal nictonic receptor subtypes
Opioid	mu, delta, kappa
Sigma	Sigma 1, 2
Histamine	H1, H2, H3
Adenosine	A1, A2A, A2, A3
Purinergic receptors	P2Y1, 2, 6, 11
Orphan GPCRs	GPR40, 41, 43
Trace amine receptors	
Melanocortin receptors	MC1-5
Corticotropin-releasing factor	CRFR1, CRFR2
Galanin	
Neurotensin	
Neuropeptide Y	Y1, Y2

[1] It is anticipated that up to 60% of samples shall be evaluated in human receptor binding assays. Samples will also be evaluated in rodent (rat, mouse) receptor binding assays.

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Patent Rights and Confidentiality of Information (Sample)

In order to assume the protection of intellectual property rights of the National Institute of Mental Health (NIMH) and/or the suppliers of compositions of matter, data, procedures, methods, product designs or manufacturing specifications to the NIMH Psychoactive Drug Screening Program, the contractor agrees to the following terms and conditions:

(a) Notwithstanding any language in any prior contract, clause, or prior agreement with any party, any intellectual property rights to any Composition of Matter (COM) submitted for testing (or any other purpose), data, procedures, methods, product designs, manufacturing specifications, or any inventions developed under this contract shall be owned by NIMH, or be assigned by the contractor to NIMH or a collaborating party[1] pursuant NIMH's determination. The contractor affirmatively disowns any claim, and will not, except as specifically instructed by NIMH in writing, seek, file, or attempt to assign any patent to any intellectual or other property rights to any such COM, data, procedures. Methods, product designs, manufacturing specifications, or any inventions developed under this contract. The contractor agrees to provide requested assistance to NIMH, at NIMH's expense, in filing and perfecting patent applications or seeking other intellectual property rights, in any patentable discoveries resulting from work under this contract.

(b) Notwithstanding any language in any prior contract, clause, or prior agreement with any party, the contractor will hold in total confidence and will not publish, release, or disclose any data, procedures, methods, or product designs or manufacturing specifications or other information developed under this contract except to the National Institute of Mental Health unless prior permission is obtained in writing from NIMH.

It is not the intent of NIMH to withhold permission to publish scientific data which cannot reasonably be considered of proprietary interest to the NIMH or any collaborating party. Consent for requests for publication shall not be withheld beyond the period necessary for NIMH or any collaborating party to establish appropriate patent or other proprietary rights. This limited right to publication of data by the contractor is subject to modification by any prior or subsequent agreement between NIMH and a collaborating party.

(c) For any subject invention arising out of the contract, which is subject to the provisions of 35 U.S.C. #200, *et seq.,* the Contractor may request NIMH to grant it additional rights in such subject invention. This request must be submitted to the Contracting Officer in writing, along with a disclosure of the subject invention and a justification for the Contractor's request. If NIMH determines that granting such additional rights will not interfere with preexisting rights of the Government or any collaborating party, any rights granted to a collaborating party as a condition of the collaboration, any co-invention rights of a collaborating party or a Government employee, or otherwise impede the ability of the Government to develop and commercialize new compounds, dosage forms, therapies, technologies or other approaches to improved treatment of mental disorders in a rapid, efficient, and cost-effective manner, NIMH shall grant the additional rights requested subject to such terms and conditions as are designed to protect the best interests of the Government.

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[1]"Collaborating Party" refers to any individual, company or other entity that participates with NIMH on the subject contract in activities, including, but not limited to, the provision of compounds, data, or methods to NIMH, for use under the contract.

Any determination by NIMH denying the Contractor requested rights in a subject invention may be appealed within 30 days of receiving notice of such decision to an agency official at a level above the person who made the determination.

(d) The Contractor agrees that violation of any of the terms listed above could give rise to a cause of action against the Contractor with damages to be determined by a court of appropriate jurisdiction.

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Standard Agreement For Submitting Compounds For Testing (Sample)

National Institute of Mental Health
Molecular and Cellular Neuroscience Research Branch
Division of Neuroscience and Basic Behavioral Science

THIS AGREEMENT, made and entered into on the _____day of _____, 2002, by and between the National Institute of Mental Health (hereinafter referred to as "NIMH") a component of the National Institutes of Health (NIH); and _____, a corporation having executive offices at _____, (hereinafter referred to as "COMPANY");

WHEREAS, COMPANY is the owner of

_____

(hereinafter referred to as "COMPOUNDS") and certain proprietary information pertaining thereto, which may be useful in the treatment of mental illness;

WHEREAS, NIMH has certain conventional pharmacological and functional assays (hereinafter referred to as "CONVENTIONAL TESTS") which may be useful in discovering compounds which have activity in the treatment of mental disorders;

WHEREAS, COMPANY wishes to have its proprietary compounds tested by NIMH in CONVENTIONAL TESTS and not administered to humans, and

WHEREAS, the parties wish to enter into arrangements to be used in the confidential testing of COMPANY compounds by NIMH;

NOW THEREFORE, the parties agree as follows:

Article 1. From time to time COMPANY will supply to a facility under contract to NIMH (hereinafter referred to as a "NIMH CONTRACTOR") or to a Government laboratory designated by NIMH, the above-mentioned COMPOUNDS and/or other compositions of matter patented or unpatented, for testing, so that NIMH may evaluate such COMPOUNDS for possible use in the treatment of mental disorders. COMPANY shall have the right to review all protocols used in testing of COMPOUNDS.

Information relating to the COMPOUNDS themselves, including their chemical structure or other identifiers, their physical properties, their biological activity, and the identity of the provider of COMPOUNDS, will be provided to NIMH by COMPANY and appropriately marked as "Confidential" (hereinafter referred to as "COMPANY CONFIDENTIAL INFORMATION"). Information will be generated on COMPOUNDS by NIMH CONTRACTORS using CONVENTIONAL TESTS (hereinafter referred to as "NIMH DATA").

Article 2. In order to facilitate the record keeping and handling of COMPANY CONFIDENTIAL INFORMATION, the parties agree as follows:

a) At the time COMPANY supplies compounds pursuant to Article 1, COMPANY shall forward to NIMH a data sheet for each COMPOUND giving pertinent available data as to chemical formula, structure, purity, solubility, melting point, other physical characteristics, stability, toxicity, and precautions which need to be followed in handling and storing of the COMPOUND. After authorization from the GPO, COMPANY shall ship the COMPOUND/S directly to the NIMH CONTRACTOR specified by the GPO.

b) The GPO will inform COMPANY which COMPOUNDS are new to NIMH and which submitted COMPOUNDS duplicate any COMPOUNDS previously existing in NIMH's structure-activity database.

c) NIMH will not disclose COMPANY CONFIDENTIAL INFORMATION unless required by law. Only those NIMH or NIMH CONTRACTOR employees with a need to know will have access to COMPANY CONFIDENTIAL INFORMATION.

d) NIMH shall require that COMPANY CONFIDENTIAL INFORMATION will be retained by NIMH CONTRACTORS, and shall not be released, published, or disclosed without the written consent of NIMH after consultation with COMPANY.

e) NIMH shall make no use of the COMPOUNDS and COMPANY CONFIDENTIAL INFORMATION other than for purposes stated in Article 1 without COMPANY's written permission.

f) NIMH shall return to COMPANY and eliminate from the NIMH testing process any COMPOUND that COMPANY may designate prior to commencement of CONVENTIONAL TESTS.

g) The foregoing restrictions on use and disclosure of COMPANY CONFIDENTIAL INFORMATION hereunder shall not apply to any information which was in NIMH's possession or control prior to the date of COMPANY's disclosure, or to any information which is in the public domain through no improper act on the part of NIMH, its employees or contractors, or which is available without restriction from any source, including COMPANY.

Article 3. COMPANY, in voluntarily supplying COMPOUNDS hereunder, is entitled to protection for the research and development work it has done and for any COMPANY CONFIDENTIAL INFORMATION, while NIMH has the responsibility to facilitate the development of medications for the treatment of mental disorders. Accordingly, the parties agree as follows:

a) NIMH agrees that all preexisting rights in those COMPOUNDS in which COMPANY has a proprietary interest shall remain in COMPANY. Inasmuch as this Agreement concerns only the evaluation of COMPANY's COMPOUNDS in CONVENTIONAL TESTS, NIMH recognizes that the mere performance of said CONVENTIONAL TESTS and nothing more does not constitute invention.

b) Contracts between NIMH and NIMH CONTRACTORS, carrying out CONVENTIONAL TESTS on submitted COMPOUNDS, will contain terms to implement the provisions of this Agreement relating to NIMH CONTRACTORS and to safeguard the rights of COMPANY under this Agreement.

c) NIMH shall be informed in writing whenever COMPANY desires to include NIMH DATA in any publication, and appropriate credit shall be given to NIMH.

Article 4. As soon as NIMH DATA is reported to NIMH, NIMH agrees to provide this information to COMPANY. If a COMPOUND is found to exhibit properties that suggest its potential usefulness in the treatment of mental disorders, NIMH will advise COMPANY to that effect.

Article 5. It is understood that COMPANY shall not be liable to the Government for any claims or damaged which shall result from the testing of COMPOUNDS while in NIMH's or the NIMH CONTRACTORS' custody, except if such claims or damages are the result of negligence on the part of COMPANY.

Article 6. In performing the CONVENTIONAL TESTS hereunder, NIMH and NIMH CONTRACTORS shall function independently and not as employees or agents of COMPANY.

Article 7. The construction, validity, performance, and effect of this Agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia.

Article 8. This Agreement shall become effective on the date hereinabove set forth.

Acceptance of the foregoing terms and conditions shall be indicated in duplicate by signatures below of the authorized representatives of each party.

COMPANY:

_____ _____
Signature Date

Name (Type or Print): _____

Title: _____

COMPANY Department: _____

COMPANY Name: _____

COMPANY Address: _____

NATIONAL INSTITUTE OF MENTAL HEALTH:

_____ _____
Authorized Official Date
NIMH/NIH

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Confidentiality And Nondisclosure Agreement (Sample)

As of this ____ day of _____, as used herein, _____ _____, is the "Disclosing Party" and the National Institute of Mental Health (NIMH), 6001 Executive Blvd. Bethesda, MD 20892, the party receiving the Confidential Information, is the "Recipient". In connection therewith, the parties agree as follows:

1. Confidential Information of the Disclosing Party may be used by the Recipient only in the review of data on a novel compound.

2. The Recipient will not, at any time, use the Confidential Information of the Disclosing Party in any fashion, form, or manner, except in furtherance of the purpose described above.

3. Each party will protect the confidentiality of the other party's Confidential Information in the same manner it protects the confidentiality of its own proprietary and confidential information of like kind. Access to the Confidential Information shall be restricted to those of each party's personnel engaged in a use permitted hereby.

4. Confidential Information disclosed hereunder shall at all times remain, as between the parties, the property of the Disclosing Party. This Agreement or any disclosure of Confidential Information grants no license under any trade secrets, copyrights, or other rights hereunder.

5. Confidential Information of the Disclosing Party may not be copied or reproduced by the Recipient without the Disclosing Party's prior written consent.

6. All Confidential Information made available hereunder, including copies thereof, shall be returned promptly to the Disclosing Party upon request of the Disclosing Party, or, at Disclosing Party's option, shall be destroyed by the Recipient.

7. Nothing in this Agreement shall prohibit or limit any party's use of information (including but not limited to ideas, concepts, know-how, techniques, and methodologies) which was (a) previously known to it, (b) independently developed by it, (c) acquired by it from a third party which was, to the Recipient's knowledge, under an obligation to the Disclosing Party not to disclose such information, or (d) which is or becomes publicly available through no breach by the Recipient of this Agreement.

8. In the event any party receives a subpoena or other validly issued administrative or judicial process demanding Confidential Information of any other party, the Recipient shall promptly notify the Disclosing Party and tender to it the defense of such demand. Unless the demand shall have been timely limited, quashed or extended, the Recipient shall thereafter be required to comply with such demand to the extent permitted by law. If requested by the party to whom the defense has been tendered, the Recipient shall cooperate (at the expense of the requesting party) in the defense of a demand. In the event the recipient National Institute of Health (NIMH) receives a request for Confidential Information under the Freedom of Information Act (5 U.S. C. 552), it will notify the Disclosing Party, and handle the request in accordance with 45 Code of Federal Regulations (CFR) 5.65.

9. Subject only to its confidentiality and non-disclosure obligations as set forth in this Agreement, each party's right to develop, use, and market products and services similar to and competitive with the Confidential Information of the other party shall remain unimpaired. Each party acknowledges that the other party may already possess or have developed products or services similar to or competitive with those of the other party disclosed in the Confidential Information.

10. No party may use the name of the other party in connection with any advertising or publicity materials or activities without the prior written consent of the other party.

11. The parties acknowledge and agree that, in the event of any breach of this agreement, the Disclosing Party might be irreparably and immediately harmed and unable to be made whole by monetary damages. It is accordingly agreed that the Disclosing Party, in addition to any other remedy to which it may be entitled at law or in equity, will be entitled to seek an injunction or injunctions to remedy breaches of this Agreement and/or to compel specific performance of this Agreement.

12. This agreement shall become effective as of the date Confidential Information is first made available to the other parties hereunder.

13. This Agreement shall be governed by Federal law. In the event of a conflict, Federal law shall control. This agreement shall be binding on each party's officers, employees, agents, successors in interest, and assigns, and shall be modified only by written agreement of the parties.

Agreed and Accepted:

_____

By: _____
(Signature)

_____
(Printed Name)

_____
(Title)

_____
(Date)

Agreed and Accepted:

National Institute of Mental Health

By: _____
(Signature)

_____
(Printed Name)

_____
(Title)

_____
(Date)

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Authority to use the following clause is being sought:

52.227-11 Patent Rights (Deviation)

This clause deviation applies to discoveries resulting from routine preclinical and clinical screening, toxicology, or synthesis activities involving the use of proprietary materials (compounds and procedures). Discoveries resulting from research activities pertaining to the development of new assays or the development or modification of chemical synthesis procedures, process development or other unanticipated discoveries developed by the contractor without the use of proprietary materials will be covered by the standard Patent Rights Clause (FAR 52.227-11, Patent Rights – Retention by the Contractor (Short Form) (June 1997)

(a) Definitions.

(1) "Invention" means any invention or discovery, which is or may be patentable or otherwise protectable under title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, *et, seq*.)

(2) "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(3) "Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statue.

(4) "Practical application" means to manufacture, in the case of a composition of matter or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(5) "Small business firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) "Subject Invention" for the purpose of this clause, means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in Section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance. It does not refer to research activities that lead to the development of new screening assays, new toxicological assays, or the development or modification of chemical synthesis procedures, process development or other discoveries not directly related to the scope of this contract. Development of new screening assays, new toxicological assays, or the

development of new chemical synthesis procedures, modification of existing procedures, process development or other unanticipated discoveries developed by the contractor without the use of proprietary compounds will not be subject to the provisions of this deviation but will be covered by the standard Patent Rights Clause which is also incorporated in this contract.

(7) "Compound Suppliers" means any entities or organizations that make available to NIMH a composition of matter or product, patented or unpatented.

(8) "NIMH" means the National Institute of Mental Health of the National Institutes of Health (NIH).

(9) "NIH" means the National Institutes of Health.

(b) *Allocation of principal rights.* (1) Retention of pre-existing rights. Compound Suppliers shall retain all pre-existing rights to those compounds in which the compound supplier has a proprietary interest.

(2) Assignment to the NIH or compound supplier. The contractor agrees to assign to the NIH or to a Compound Supplier designated by NIMH the entire right, title, and interest throughout the world to each subject invention except to the extent that rights are retained by the contractor under subparagraph (b)(3) of this clause and subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the United States Government to practice or have practiced the subject invention for or on behalf of the United States throughout the world.

(3) Greater Rights Determinations. The contractor, or an employee-inventor after consultation by the NIMH with the contractor, may request greater rights to an identified subject invention of the contract in accordance with the procedures of FAR paragraph 27.304-1(b) and (FAR paragraph 27.304-1(c)) in the case of an employee-inventor). The NIMH will grant greater rights if the supplier is not interested in developing the invention. In addition to the considerations set forth in paragraph 27.304-1(b), NIMH will consider whether granting the requested greater rights will interfere with rights of the Government or any Compound Supplier or otherwise impede the ability of the Government or the Compound Supplier to develop and commercialize new compositions of matter, compounds, product designs, dosage forms, therapies, technologies or other approaches for the treatment of mental disorders in a rapid, efficient, and cost-effective manner. A request for a determination of whether the contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the NIMH Contracting Officer at the time of the first disclosure of the invention pursuant to subparagraph (c)(1) below, or not later than eight (8) months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13, and to any reservations and conditions deemed to be appropriate by NIMH such as the requirement to assign or exclusively license the rights to subject inventions to the Compound supplier. A determination by NIMH denying a request by the contractor for greater rights in a subject invention may be appealed within 30 days of the date the contractor is notified of the determination to any agency official at a level above the individual who made the determination. If greater rights are granted, the contractor must file a patent application on the invention. Upon request, the contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any subject invention in any country for which the contractor has retained title. Upon request, the contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) *Invention disclosure by contractor.* The contractor will disclose each subject invention to the NIMH Contracting Officer as provided in paragraph (j) within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the NIMH Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(d) *Contractor action to protect the Government's interest. (1)* The contractor agrees to execute or to have executed and promptly deliver to the NIH all instruments necessary to – (i) Establish or confirm the rights the Government has throughout the world in subject inventions pursuant to paragraph b.2. above, and (ii) Convey title to the NIH or to a Compound Supplier when requested under paragraph b.2. of this clause and to enable the NIH or a Compound supplier to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's right or a Compound Supplier's right in the subject inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars. The contractor will notify the NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response period required by the relevant patent office.

(3) The contractor agrees to include, within the specification of any United States patent application it files and any patent issuing thereon covering a subject invention the following statement, "This invention was made with Government support under (identify the contract) awarded by the National Institute of Mental Health. The Government has certain rights in the invention."

(4) The contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all subject inventions or stating that there were none.

(e) *Subcontracts.* (1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental, or research work. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's subject inventions.

(2) In the case of subcontracts, at any tier, NIH, the subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the

subcontractor and NIH with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13 which is incorporated by reference in paragraph b.3 of this clause.

(f) *Reporting on utilization of subject inventions in the event greater rights are granted to the contractor.* The contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees when the NIH has granted a request under subparagraph b.3. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the NIH in connection with any march-in proceeding undertaken by the NIH in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the NIH agrees it will not disclose such information to persons outside the Government without permission of the contractor.

(g) Preference for United States industry in the event greater rights is granted to the contractor. Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the NIH upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights in the event greater rights are granted to the contractor. The contractor agrees that, with respect to any subject invention in which it has acquired title through the exercise of the rights specified in subparagraph (b)(3), the NIH has the right in accordance with the procedures in FAR paragraph 27.304-1 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the NIH has the right to grant such a license itself if the NIH determines that—

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) Such action is necessary because the agreement required by paragraph (g) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(i) *Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the contractor.* If the contractor is a nonprofit organization, it agrees that—

(1) Rights to a subject invention in the United States may not be assigned without the approval of the NIH, except where such assignment is made to an organization which has as one of its primary functions the management of inventions; provided, that such assignee will be subject to the same provisions as the contractor;

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the NIH deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e);

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses, (including payments to inventors) incidental to the administration of subject inventions will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms, and that it ill give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary of Commerce may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the contractor could take reasonable steps to more effectively implement the requirements of this subparagraph.

(j) Communications. All invention disclosures and requests for greater rights shall be sent to the NIMH Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications should be sent to the Office of Extramural Inventions and Technology Resources Branch, OPERA, National Institutes of Health, Rockledge, II, 6701 Rockledge Drive, Room 3190, MSC 7750, Bethesda, MD 20892-7750

(End of Clause)

PART I

ATTACHMENT 2
April 21, 2003
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EVALUATION CRITERIA FOR AWARD

A. GENERAL - BASIS FOR AWARD

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors in order of importance are: technical, cost, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

B. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

C. TECHNICAL EVALUATION CRITERIA

The technical evaluation group (TEG) will use the following evaluation criteria when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Proposals submitted in response to this RFP will be judged solely on the written material provided by the offeror. The maximum score for a proposal is **115** Points.

1. TECHNICAL APPROACH — 60 points

a. Demonstrated state-of-the-art quality, soundness, feasibility, and reliability of the offeror's experimental procedures for validating radioligand binding and enzyme assays for human and rodent CNS receptors. Assay characteristics (e.g., cell type/source of receptor, radioligand, ligand used for non-specific binding, specific binding, K_D, B_{max}), literature citation for the assay, competition curves (graphs) and summary data for reference compounds (e.g., IC_{50}, K_i) should be provided for each of the pharmacological assays of interest listed in Appendix 1 in the form of an **assay protocol book.** The choice of radioligand, assay protocol, and reference compounds should be discussed. Assay

characteristics (specific binding, K_D, B_{max}) should be compared to values in the scientific literature. Curve-fitting programs or methodologies used for quantitative analysis of receptor binding data should be demonstrated. **(0-20 points)**

b. State-of-the-art quality, soundness, feasibility, and reliability of the offeror's experimental procedures for validating functional assays for human and rodent CNS receptors. Presentation and discussion of functional assays to assess agonist and antagonist properties and reference compounds chosen for validation of functional assays for the receptors of interest listed in Appendix 1. Assay characteristics (e.g., cell type/source of receptor, choice reference compounds, assay protocol, literature citation) should be presented and discussed. Validation data for the functional assays (e.g., uptake, G-protein coupling, second messenger assays) shall be provided in the form of an **assay protocol book** consisting of graphs of the reference compounds and summary data (e.g., EC_{50}, IC_{50} values) for each of the assays. Curve-fitting programs or methodologies used for quantitative analysis of data should be demonstrated.
(0-20 points)

c. Presentation and discussion of state-of-the-art quality, soundness, and feasibility of the offeror's experimental approaches to develop and validate pharmacological and functional assays for newly discovered receptors (e.g., capabilities to clone receptors, verify the sequences, etc.)
(0-20 points)

2. PERSONNEL **20 points**

a. Availability and competence of the offeror's proposed personnel. Demonstrated expertise and experience in screening synthetic compounds and natural products in CNS receptor and enzyme assays and analysis and interpretation of data as evidenced by peer-reviewed scientific publications. Demonstrated expertise and experience in screening compounds in functional assays and analysis and interpretation of data in G-protein coupling, monoamine uptake, and second messenger assays as evidenced by peer-reviewed scientific publications. Demonstrated expertise and experience in state-of-the art molecular biological, pharmacological, and biochemical techniques as applied to the development and validation of new CNS receptor assays.

b. Demonstrated state-of-the-art knowledge in the areas of molecular pharmacology, biochemistry (e.g., functional assays), radiochemistry, and the development of drugs for use as PET ligands, tools for basic and clinical research, and the treatment of mental disorders.

c. Availability of the necessary expertise for database set-up and maintenance.

3. DATA MANAGEMENT APPROACH **20 Points**

a. Quality control procedures to ensure data reliability and reproducibility, including discussion of anticipated major experimental problems and limitations together with suggested solutions.

b. Technical approach for the set-up and maintenance of a searchable, web-based database of binding affinities (Ki values) and radiotracers. Approach for regular updates of the databases and addition of new data. Approach for making the databases open and accessible to the public. Approach for the design and maintenance of the program website.

4. FACILITIES AND ORGANIZATIONAL MANAGEMENT 15 Points

a. The offeror's description of facilities and list of equipment, including IR, will be assessed for its availability to the project, and suitability for these studies. Provide a floor plan.

b. Plans to organize the work, administer the project, coordinate the resources, and ensure time commitments are met including, staff hours or days planned per week. Discuss any activities to be subcontracted, and the logistics involved. Provide an organizational chart delineating clear lines of authority, areas of management for specific tasks, reporting responsibilities, coordination with NIMH, and quality control procedures. Discuss priority to be given to this work in relation to other commitments.

Total points 115 Points

D. PAST PERFORMANCE FACTOR

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award consideration based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

You must send evaluation forms (see attachment 5) to all client/customers listed in the business proposal, to support a past performance evaluation by the Government.

E. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

PART II

ATTACHMENT 3
April 21, 2003
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INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

Preface: This attachment is intended to provide specific instructions to offerors in order to facilitate preparation of a proposal for this solicitation.

In order to limit the size of this file, we have *linked* the large body of very detailed instructions (referred to as "Section L" on the NCI internet site, below), which should be reviewed prior to completing your offer.

Sections I-III, below, are explained as follows:

> **Section I** (A-D) *completes/updates* certain items in the linked instructions that are specific to this acquisition. The item numbers below correspond to like numbered items in the linked instructions (i.e., item 2 corresponds to item 2 in the linked instructions).
>
> **Section II** is provided to summarize the content and format of the technical and business proposals.
>
> **Section III** explains the performance-based measures, which will be used to evaluate the quality and timeliness of work performed under this contract.

I. The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

A. General Information

- ***Item 2:*** **Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISITION**, is applicable to this solicitation.

- ***Item 5:*** **JUST IN TIME PROCEDURES** are applicable to this solicitation.

  The submission of an acceptable subcontracting plan ☐ is, ☒ is not required with your proposal.

  If a subcontracting plan is required from your organization:

  ☐ It will be requested from only those offerors in the competitive range.
  ☒ It will be requested from only the apparent successful offeror.

- ***Item 8:*** **NAICS CODE AND SIZE STANDARD:**

  Note: The following information is to be used by the offeror in preparing its Representations and

Certifications (See attachment 4 of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The NAICS Code is: **541710**
(2) The small business size standard is: **500**

- ***Item 10:*** **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS.**

  Offerors will be evaluated by adding a factor of **10%** to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

- ***Item 11:*** **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

  It is anticipated that *one (1) award* will be made for this solicitation and that the award will be made on or about ***September 30, 2003.***

  It is anticipated that the award from this solicitation will be a multiple-year, ***cost-reimbursement (completion) contract, with a fixed-price*** *component*, and that ***incremental funding*** will be used. [See Section L, PART IV-Business Proposal Instructions.]

- ***Item 13:*** **ESTIMATE OF EFFORT**

See **II. Supplementary Technical and Business Proposal Instructions (B. Business Proposal Instructions)** below.

- ***Item 16:*** **COMPARATIVE IMPORTANCE OF PROPOSALS**

  You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are *significantly more important than cost or price*. The relative importance of the evaluation factors is specified in SECTION M (**Attachment 2**) of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

- ***Item 20:*** **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70** is applicable to this solicitation.

B. General Instructions

- ***Item 23:*** **Potential Award Without Discussions** is applicable to this solicitation.

- ***Item 29:*** **Small Business Subcontracting Plan** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

  The following are the NIH-wide small business subcontracting goals, and are provided as a guide for this RFP: **23%** for Small Business; **5%** for Small Disadvantaged Business; **5%** for Women-Owned Small Business; **2.5%** for HUBZone Small Business; and **3%** for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

- ***Item 31:*** **Extent of Small Disadvantaged Business Participation** is applicable to this solicitation.

- ***Item 33:*** **Salary Rate Limitation in fiscal year 2003** is applicable to this solicitation.

- ***Item 36:*** **Past Performance Information** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

  Past Performance information shall be submitted as part of the ***Business*** proposal. A list of the *all contracts* completed during the past ***three (3)*** years and ***all contracts*** currently in process that are considered similar in nature to the solicitation workscope.

- ***Item 45:*** **Solicitation Provisions Incorporated by Reference:** The following provisions are applicable to this solicitation.

  Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997) (*applies only if your organization is a commercial entity).*

  Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

  Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

C. Technical Proposal Instructions

- ***Item 47:*** **Project Objectives, NIH-1688-1**, is applicable to this solicitation.

D. Business Proposal Instructions

- ***Item 52:*** **Information Other than Cost or Pricing Data** is applicable to this solicitation.

  ☒ This information may be submitted in the offeror's own format.
  ☐ This information shall be submitted in the following format:

  If your proposal is included in the Competitive Range for negotiations, you will be required to submit documentation verifying labor rates/costs, selected items of other direct costs (to be specified by the Contracting Officer) fringe benefits, and all indirect costs.

  A narrative explanation of how the level of effort and costs were developed, including any assumptions made/used, will also be required.

  This information does not have to accompany your initial proposal, but if requested you must be able to promptly submit this data.

- ***Item 53:*** **Level of Detail-Cost Information** is applicable to this solicitation.
  The information required for this solicitation is supplemented and/or changed as follows:
  (See item 52 above)

- ***Item 55:*** **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data, FAR Clause 52.215-20**, is applicable to this solicitation.

- ***Item 60:*** **Incremental Funding** is applicable to this solicitation.

II. Supplementary Technical and Business Proposal Instructions

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A. Technical Proposal – for detailed instructions see Technical Proposal Instructions at: http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

As specified in the above NCI website, please format your technical proposal as follows:

Format of Technical Proposal:

a. Technical Proposal Cover Sheet
b. Government Notice for Handling Proposals (as applicable)
c. Title Page
d NIH form "Project Objectives, NIH-1688-1"
e. Statement of Work (outline and detail how your organization will accomplish the work required – the sections are listed below)
   (1) Objectives
   (2) Approach
   (3) Methods **[include the "assay protocol book" (as discussed in Attachment 2) for all assays, together with a detailed narrative discussion]**
   (4) Schedule
f. Personnel
   (1) Principal Investigator/Project Director
   (2) Other Investigators
   (3) Additional Personnel
   (4) Resumes
g. Other Considerations
   (1) Any agreements and/or arrangements with subcontractor(s).
   (2) Unique arrangements, equipment, etc.,
   (3) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
   (4) Other factors you feel are important and support your proposed research.
   (5) Recommendations
h. Other Forms
   Include the remaining applicable forms linked in **Attachment 4:**
   - Technical Proposal Cost Summary
   - Summary of Current and Proposed Activities.

B. Business Proposal - for detailed instructions see Business Proposal Instructions at: http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

While the business proposal can be submitted in the offeror's own format, it must, at a minimum, show detailed costs by individual (with hrs./ percent effort) and by cost category, by year, with an accompanying narrative explanation and justification stating how the costs were estimated, i.e., the basis of the estimated costs. **A requested format is provided below.**

Note regarding Fee: If you are a commercial organization (or a not-for-profit research organization which can receive a fee), you must propose a "total" fee, portioned into a "base" fee and "award" fee

(note: the award fee portion is typically larger than the base fee portion); the amount of total fee is negotiable, and the proportion of base fee vs. award fee. Fee should be based upon the risk involved and complexity of the work. Please carefully read the Performance Standards and Measures Chart and the CPAF Contract Rating Table (with the Statement of Work, **attachment 1**).

1. Important Cost/Price Information and Charts

a. This effort/work is composed 3 parts, for *accounting* purposes: 1) Fixed price portion (the assay tasks 2-4); 2) Cost-reimbursement portion (tasks 1, 5-9); and 3) Optional Task 10.
Each part is discussed below.

b. For cost proposal purposes, assume the following mix for tasks 1-9: 80% of the total costs will be on tasks 2-4 (fixed-price), and 20% on tasks 1, 5-9 (cost-reimbursement). The level of effort necessary for the cost-reimbursement tasks, excluding optional task 10, is *estimated* at 4,578 hrs. (see chart above). Task 10 will be cost reimbursement also (see chart below), but is not included in the above mix or hours.

c. Provide costs/prices for ALL three (3) parts separately in the business proposal, and cumulate them for a grand total.

2. Fixed price portion (the assay tasks, 2-4)

Please submit charts/spreadsheets similar to the following in the business proposal for these fixed-price tasks. **For assay 4, base your proposal amount as specified below.**

Chart 1 - Fixed Price Per Assay (Tasks 2-4)

Task No.	Assay Type	Estimated number/year	Estimated Cost/Assay	Total Estimated Cost
Task 2c	Primary Assays	5000		
Task 2d	Secondary Assays	800		
Task 3	Functional Assays	525		
*Task 4	Bioavailability-Caco-2 cell assay	200		
	Provide Prices, But Do Not Include in Total Cost in Business Proposal ↓			
Task 4	Blood Brain Barrier Penetrance Assays			
Task 4	Plasma Protein Specific Binding			
Task 4	LogP Predicitve Assays			
Task 4	Cardiac Toxicity Assays			
Task 4	QSAR/QSPR Modeling			

* Use this assay type and estimated number of assays per year in your business proposal.

Chart 2 – Assay Cost Data - Fixed Price Assays

Also complete the following chart showing the costs for each type of assay:

Assay____	Base: Year 1	Year 2	Year 3	Options: Option 1	Option 2
Direct Labor*					
Fringe Benefits					
Other Direct Costs (list): - Computer - Matl. & Supplies - Consultants - Travel - Other					
Equipment					
Subcontracts					
Indirect Costs					
Total Costs					
Fee: Base Fee					
Award Fee					
Total Fee					
Total Assay Cost					

3. Cost-reimbursement Portion (Tasks 1, 5-9)

An Excel spreadsheet is provided at http://ocm.od.nih.gov/contracts/rfps/FORMS1.HTM which may be used to present these costs, or the offeror can use their own spreadsheet.

Note: It is very useful to provide an electronic copy of the spreadsheet used to prepare the business proposal, either via E-mail or on a disc, with the business proposal.

Chart 3 - Cost-reimbursement Chart (Tasks 1, 5-9)

Work for the cost-reimbursement tasks should be presented in a format similar to the following, (with accompanying detail):

Cost Element	Base: Year 1	Year 2	Year 3	Options: Option 1	Option 2
Direct Labor*					
Fringe Benefits					
Other Direct Costs (list): - Computer - Matl. & Supplies - Consultants - Travel - Other					
Equipment					
Subcontracts					
Indirect Costs					
Total Costs					
Fee: Base Fee					
Award Fee					
Total Fee					
Grand Total					

Note: To assist you in the preparation of your proposal, the Government considers the annual effort to be approximately ***4,578*** labor hours. This does not include hours for Optional Task 10, below. **This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.**

Chart 4 - Effort Chart (Tasks 1, and 5-9)

Category/Description	**Annual Estimated Hours**
Principal Investigator	418
Administrative/Programming	2080
Technician	1040
Technician	1040
Total	**4,578**

Note: 1 FTE = 2,080 hours in the above chart

4. Task 10 - Compound Library Screening (Optional)

Please provide cost estimates for Task 10, Compound Library Screening (Optional), for each of the scenarios in the chart below. **If exercised, this option will also be invoiced as cost-reimbursement during the contract.**

For evaluation purposes, use scenario #6 (100,000 compounds, 40 assays/compound, over 2 years) of this option in your total contract amount; provide costs for all scenarios.

Chart 5 - Compound Library Screening (Optional Task 10)

Complete this chart for all scenarios, but provide detail on scenario #6 below

Scenario No.	**Number of Compounds Screened**	**Number of Assays per Compound**	**Approximate Completion Time**	**Estimated Cost**
1	50,000 Compounds	40 assays	1 year	
2	50, 000 Compounds	40 assays	2 years	
3	50,000 Compounds	100 assays	2 years	
4	50, 000 Compounds	100 assays	3 years	
5	100,000 Compounds	40 assays	1 year	
6*	100,000 Compounds	40 assays	2 years	
7	100,000 Compounds	100 assays	2 years	
8	100,000 Compounds	100 assays	3 years	

*** Use cost for this scenario in the total contract amount proposed**

Chart 6 - Compound Library Screening (Scenario #6) Optional Task 10 (Cost Breakdown)

Complete this chart for scenario 6, breaking out the costs.

Task 10, Scenario 6	Base: Year 1	Year 2
Cost Element		
Direct Labor*		
Fringe Benefits		
Other Direct Costs (list): - Computer - Matl. & Supplies - Consultants - Travel - Other		
Equipment		
Subcontracts		
Indirect Costs		
Total Costs		
Fee: Base Fee		
Award Fee		
Total Fee		
Grand Total		

5. Suggested Format of Business Proposal:

a. NIH-2043, Proposal Summary and Data Record
b. Government Notice for Handling Proposals (as applicable)
c. Cover Page
d. Cost Charts **(see above)**
e. Narrative discussion of each cost element and how costs were developed.
f. Past Performance data **(you must send evaluation forms in attachment 5, to all clients listed)**
g. Include these linked forms (**see Attachment 4**):
- Disclosure of Lobbying Activities, OMB SF-LLL (one copy)
- Representations and Certifications (one copy).

h. Financial statements, travel policy, personnel policies, and details about your accounting system: these will be requested if the offeror makes the competitive range.

III. Performance-Based Measures/ Conditions (Sample Contract Language)

The following two clauses provide additional information relating to the award fee terms and conditions, which will be employed under this contract. These clauses may become part of any resultant contract (they are provided for informational purposes only).

A. [In Section B of the contract]

ARTICLE B. . ESTIMATED COST, FIXED FEE AND AWARD FEE

a. The total estimated cost (exclusive of any fees) of this contract, including direct and indirect costs, is $____.

b. The fixed-fee for this contract is $____. The fixed-fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED-FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed-fee shall be made in equal monthly installments.

c. The maximum amount of Award Fee that may be earned on the contract is $____. Award fee earned shall be based upon an evaluation and determination by the Government as to the Contractor's level of performance in accordance with the following procedures:

(1) The Contractor's performance shall be evaluated on a semi-annual basis, (every six months) during the period of the contract. The award fee evaluation periods and maximum amounts for each are listed in Section H, Special Contract Requirements, Award Fee.

(2) The criteria set forth in the Quality Assurance Surveillance Plan**,** included in Section) H, Special Contract Requirements, Award Fee, shall be used to evaluate the Contractor's performance.

(3) The Contractor further agrees that the final determination as to the amount of Award Fee earned will be made by the Contracting Officer, taking into consideration an analysis and evaluation of the Contractor's performance made by the Award Fee Evaluation Group described in ARTICLE H. (of the resulting contract) and shall not be subject to the terms of the "Disputes" clause of this contract. The Contractor shall be advised in writing of the decision setting forth reasons why the Award Fee was earned, or why it was not earned, in order that the Contractor may improve its performance during the next six (6) months, if the latter is applicable.

(4) Notwithstanding any other provisions of this contract, the fee for performing this contract shall not exceed the statutory limitations prescribed in the first sentence of Section 304(b) of the Federal Property and Administrative Services Act (41 U.S.C. 254(b)) for services other than research, development or experimental work.

(5) Authorization to claim and be reimbursed for Award Fee under this contract will be accomplished by an Administrative Modification, executed by the Contracting Officer, when the Award Fee, if any, has been determined to be due. The Administrative Modification shall set forth the amount of award fee to be paid and shall indicate the performance period evaluated. Upon receipt of the contract/modification, the Contractor may submit a public voucher for payment of the total Award fee earned for the period evaluated. Payment of the Award fee shall be subject to the withholding provision of the clause entitled "Fixed Fee."

d. The Government's maximum obligation, represented by the sum of the estimated cost, fixed-fee, and award fee $_____.

e. Total funds currently available for payment and allotted to this contract are $___, of which $____ represents the estimated costs, $____ the fixed-fee and $____ the possible award fee. For further provisions on funding, see the LIMITATION OF FUNDS clause incorporated herein.

f. The amounts negotiated (and anticipated incremental funding schedule) for this contract are as follows:

Period of Performance	Estimated Cost	Fixed Fee	Award Fee Possible	Total Est. Cost Plus Fees
Year 1				
Year 2				
Year 3				
Option 1				
Option 2				

g. It is estimated that the amount currently allotted will cover performance of the contract through ___.

h. The Contracting Officer may allot additional funds to the contract without the concurrence of the contractor.

B. [In Section H of the contract]:

ARTICLE H. AWARD FEE

Evaluation Guidelines And Procedures For A Performance Based Cost-Plus Award-Fee (PBCPAF) Contract

A. Purpose

The purpose of this document is to establish a proposed procedure for evaluating the Contractor's performance. The evaluation will be conducted on a semi-annual basis (twice a year), and the Contractor's Award Fee will be based on the quality of services provided, inclusive of deliverables, using a numerical scale. If the rating for services falls below ____, the Contractor will not receive an award for the rating period.

1. The key factors in the technical evaluation will be quality of the service, responsiveness of the Contractor to requirements, compliance with deliverable schedules, cost containment and customer service response, as reflected in the Work Statement.

2. Criticism should be constructive in all points, and should be directed toward improvement of operations in conformance with Government objectives and requirements.

B. Contractor's Responsibilities

The Government's decision to pay or not to pay Award Fee in no way alters the contractor's responsibilities to perform any functions or produce any deliverables required by this contract, or the Government's obligation to pay the contractor for satisfactory deliverables in accordance with this contract. Annual amounts available for Award Fee are identified in Section B.

C. Responsibilities of the Award Fee Evaluation Group

1. The award of fee will be made semi-annually, and will be based upon objective evaluation of the Contractor's performance by an Award Fee Evaluation Group to be established after award of the contract. The group will evaluate the Contractor's performance by assessing the Contractor's completion of requirements. The group's evaluation will be made by rating the Contractor's technical performance using all sources available. It is anticipated that the Award Fee Evaluation Group will consist of the Project Officer, program staff, and contract staff.

2. The award fee group will give the project a numerical rating (0-100 points) and will report to the Contracting Officer the amount of award fee recommended for payment to the Contractor for the preceding six-month contract period.

3. The Contractor may express disagreement with the Award fee determinations through a letter to the Contracting Officer. The Contractor's comments will be taken into consideration in the subsequent evaluation; however, the previous fee evaluation determination will not be changed or amended and the decision of the Contracting Officer will be final.

4. The payment of award fee will be made after a written administrative directive is prepared and signed by the Contracting Officer, and an invoice is received from the Contractor for such earned fee.

D. Anticipated Results of the PBCPAF Contract

1. The overall guiding purpose of the PBCPAF mode of contracting is to provide a strong incentive for the Contractor to achieve superior performance. It allows the Contractor flexibly in performing the work and promotes maximum cooperation between the Contractor and the Government.

2. It is anticipated that the criteria utilized in the evaluation of technical achievement for determination of award fee will encourage the Contractor's enthusiastic cooperation and participation in improving the work performed.

3. It is also anticipated that the operations of the Award Fee Evaluation Group will establish and maintain a working relationship between the Government and the Contractor that will be produce a good business environment and will stimulate free exchange of relevant information. The Award Fee Evaluation Group operation will provide for the clear establishment of priorities and relative importance of various work elements of the program. This will assist the Contractor in its efforts to meet the requirements of the contract and will provide the necessary guidance to ensure the maximum return to the Government for its investment.

The group will include with its numerical evaluation, a corresponding narrative that supports the score. In developing remarks, the primary frame of reference will be typical performance trends throughout all or a significant portion of the project evaluation period. However, specific examples of performance may be used for clarification and emphasis. Remarks will explain reasons for an increase or decreases of the technical achievement ratings as well as a justification for the ratings provided.

E. CPAF Contract Rating Table

The Award Fee Evaluation Group will evaluate the quality of the services provided using a numerical rating scale from 0 to 100. [**See rating table in Attachment 1.]**

PART III

ATTACHMENT 4
April 21, 2003
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APPLICABLE RFP REFERENCES/FORMS/WEB LINKS

A. Sample Contract Format- General

The website below outlines a "typical" format for Sections B-J of a contract document. This schedule is provided for informational purposes only. The contract schedule set forth in the website below contains information pertinent to many types of R&D solicitations done at the NIH. The Schedule is not an exact representation of the proposed contract document. For example, contractual provisions pertinent to an Offeror's organizational structure (e.g., Non-Profit, Commercial) and specific costs requiring Contracting Officer prior approval will be negotiated and included in the contract.
http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

B. General Clauses and Provisions

The following general clauses and provisions are applicable to this specific RFP and are located on-line at the URL: http://rcb.cancer.gov/rcb-internet/clauses/clauses.html

Any resultant contract will include clauses applicable to your particular type of institution (e.g. educational, for-profit etc.). These clauses are provided for informational purposes only, but may be discussed during negotiations.

C. Forms, Formats And Attachments

The following items are applicable to this specific RFP and are located on-line at URL http://ocm.od.nih.gov/contracts/rfps/FORMS1.HTM under the heading Forms, Formats and Attachments.

1. Submit With Technical Proposal

(Submit with original and each copy of technical proposal)

a. Technical Proposal Cover Sheet
b. NIH form "Project Objectives, NIH-1688-1"
c. Government Notice for Handling Proposals (as applicable)
d. Summary of Current and Proposed Activities
e. Technical Proposal Cost Summary

2. Submit With Business Proposal

(Submit with original and each copy of business proposal)

a. Proposal Summary and Data record, NIH-2043

b. Business Proposal Cost Information (or other Cost spreadsheet in offeror's format); must show costs and hours/percent effort, by year, by individual and cost category); see linked Excel spreadsheet at http://ocm.od.nih.gov/contracts/rfps/FORMS1.HTM
c. Fixed Price Cost Per Assay Chart (attached below)

(Submit with original copy of business proposal only)

d. Disclosure of Lobbying Activities, OMB SF-LLL
e. Representations and Certifications

3. Other Forms Or Documents - To Be Submitted Later:

a. Certificate of Current Cost or Pricing Data, NIH-1397 (to be submitted with FPR, if required by the CO).
b. Small Business Subcontracting Plan (to be submitted as directed by the CO).

4. Proposal Intent Response Sheet (Attached, Below)

5. Anticipated To Be Included As Contract Attachments:

a. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
b. Procurement of Certain Equipment, NIH(RC)-7
c. Small Business Subcontracting Plan

D. Other web links that may be useful to offerors:

Website	Description
http://farsite.hill.af.mil/vffar1.htm	FAR
http://www.hhs.gov/ogam/oam/procurement/hhsar.html	HHSAR
http://www.eps.gov/	FedBizOpps
http://www.wifcon.com/	Where in Federal Contracting?
http://firstgov.gov/	First Gov
http://www.nimh.nih.gov/	NIMH
http://www.nih.gov/index.html	NIH
http://www.os.dhhs.gov/	DHHS
http://www.whitehouse.gov/omb/grants/	OMB

http://www.opm.gov/oca/PAYRATES/index.htm	Executive Schedule Salaries
http://www.grants.nih.gov/grants/olaw/olaw.htm.	Animal Welfare Regs
http://www.cdc.gov/od/sap/.	Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins
http://ott.od.nih.gov/NewPages/64FR72090.pdf.	"Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts,"
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html	NIH's data sharing policy
http://www.sba.gov/hubzone.	HUBZone Firms
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm	listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions
http://policyworks.gov/org/main/mt/homepage/mtt/perdiem/perd03d.html	Domestic Per Diem Rates (GSA)
http://www.ccr.dlis.dla.mil	Central Contractor Registration (CCR)

PROPOSAL INTENT RESPONSE SHEET
April 21, 2003
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PLEASE FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **May 6, 2003**. YOUR EXPRESSION OF INTENT IS *NOT* BINDING, BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

☐ DO INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING:

"NIMH Psychoactive Drug Screening Program"

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

_____
_____
_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)

_____
_____
_____
_____

RETURN TO: National Institute of Mental Health, NIH
Contracts Management Branch
Attn: Bruce E. Anderson
Neuroscience Center Bldg., Rm. 8155
6001 Executive Blvd. (MSC 9661)
Bethesda, MD 20892-9661
FAX (301) 443-0501
ba9i@nih.gov

ATTACHMENT 5
April 21, 2003
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CUSTOMER PAST PERFORMANCE QUESTIONNAIRE

NIMH
National Institute of Mental Health

From: **Contracting Officer, NIH**

To: **Client/Customer Organization**

Re: **Past Performance Evaluation**

Your organization has been cited as a "customer" of the organization sending you this form, in a recent contract proposal to the NIMH.

As a customer, please complete the form below, evaluating the work provided to your organization, and return directly to the NIMH Contracting Officer (Fax or E-mail is acceptable) at:

ATTN: Bruce E. Anderson
Contracting Officer
National Institute of Mental Health
Contract Management Branch
6001 Executive Blvd., Rm. 8155 (MSC 9661)
Bethesda, MD 20892
(301) 443-2234
Fax: (301) 443-0501
E-Mail: ba9i@nih.gov

As background, the NIMH requirement can be summarized as follows: The purpose of the NIMH Psychoactive Drug Screening Program is to provide pharmacological and functional screening of novel synthetic compounds and natural products for potential use as PET, SPECT, and fMRI ligands for functional brain imaging, research tools or probes for basic and clinical research, and therapeutic agents for mental disorders. This screen is not intended for the purpose of large-scale, random screening of natural products or combinatorial libraries but as a screen for compounds that have previously been shown to possess pharmacological, biochemical, or behavioral activities relevant to NIMH. The objectives of the contract are to receive and test approximately 1,000 (but could range from 500-1,500) coded samples (synthetic compounds, small molecules, gene products, and natural product extracts) per year, as specified by the GPO, in broad-based human and rodent CNS receptor and enzyme screening assays, to test active samples in secondary functional assays, and to provide an electronic data file for each of the screened compounds.

Thanks for completing this form.
/s/
Bruce E. Anderson
Contracting Officer, NIMH, NIH, DHHS

Customer/Client Contract Data

Evaluating Organization: ***The customer which received the services***	**Reporting Period: From** **to** ***Dates services were provided***	
	Contract Number: **Contract Type:**	**Order Number:**

Is/was the work provided to you by this organization similar/comparable to the NIMH requirement above?

☐ Yes ☐ In Part ☐ No

(Explain if "In Part" or "No" is checked):

Contractor Name: ***The organization which provided the services***	**Contractor Address:**	
	City:	**State:**
Contract Award Date:	**Contract Expiration Date:**	**Contract Value:**
Requirement Description: ***Title and brief description of the contract/services***		

Client Ratings

Summarize contractor performance and check the number that corresponds to the rating for each rating category (double click the check-box) (*See attached Rating Guidelines).*

Quality of Product or Service

☐ **0=Unsatisfactory** ☐ **1=Poor** ☐ **2=Fair** ☐ **3=Good** ☐ **4=Excellent** ☐ **5=Outstanding**

Comments for Quality of Product or Service:

Cost Control (*Rating and Comments for Cost Control <u>are not</u> required if contract type is Fixed-Price)*

☐ **0=Unsatisfactory** ☐ **1=Poor** ☐ **2=Fair** ☐ **3=Good** ☐ **4=Excellent** ☐ **5=Outstanding**

Comments for Cost Control:

Timeliness of Performance

☐ **0=Unsatisfactory** ☐ **1=Poor** ☐ **2=Fair** ☐ **3=Good** ☐ **4=Excellent** ☐ **5=Outstanding**

Comments for Timeliness of Performance:

Business Relations

☐ 0=Unsatisfactory	☐ 1=Poor	☐ 2=Fair	☐ 3=Good	☐ 4=Excellent	☐ 5=Outstanding

Comments for Business Relations:

Additional Info

Subcontracts

Are/were subcontracts involved? ☐ **Yes** ☐ **No (*Check one)***

Comment on subcontracts:

To your knowledge, did the Contractor utilize any subcontractors who were small businesses, small disadvantaged businesses, woman-owned businesses, veteran-owned small businesses, HUBZone small businesses?

☐ **Yes** ☐ **No** ☐ **N/A** ☐ **Not sure (*Check one)***

Contractor Key Personnel

1. Contractor Manager/Principal Investigator (*name):*

Comments on Contractor Manager/Principal Investigator:

2, Other Contractor Key Personnel (*name/list):*

Comments on Contractor Key Person:

Subcontracting Plan (Government clients only)

Small Business Subcontracting Plan (to be completed by Government clients only)

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, reporting and other aspects of the plan? ☐ **Yes** ☐ **No** ☐ **N/A (*Check one)***

Government Comments on Small Business Subcontracting Plan:

Small Disadvantaged Business Goals (to be completed by Government clients only)

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, for small disadvantaged business (SDB) participation, monetary targets for SDB participation, and required notifications? ☐ **Yes** ☐ **No** ☐ **N/A (*Check one)***

Government Comments on Small Disadvantaged Business Goals:

Customer Satisfaction

Is/was the contractor committed to customer satisfaction? ☐ **Yes** ☐ **No (*Check one)***

Would you select this firm again? ☐ **Yes** ☐ **No (*Check one)***

Comments on Customer Satisfaction:

Admin Info

Your Organization's Technical Contact (Client)
Name:
Phone:
Fax:
E-mail Address:

Your Organization's Business Representative (Client)
Name:
Phone:
Fax:
E-mail Address:

Rating Guidelines

Quality of Product or Service

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Non-conformances are jeopardizing the achievement of contract requirements. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards containing similar requirements.
Poor	Overall compliance requires significant customer resources to ensure achievement of contract requirements.
Fair	Overall compliance requires minor customer resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, quality problems, and the Contractor has met the contract requirements.
Excellent	There are no quality issues, and the Contractor has substantially exceeded the contract performance requirements without commensurate additional costs to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that was significantly in excess of anticipated achievements and is commendable as an example for others, so that it justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Cost Control

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of customer resources. Recovery is not likely. If performance cannot be substantially corrected, this level of ability to manage cost issues constitutes a significant impediment in consideration for future awards.
Poor	Ability to manage cost issues requires significant customer resources to ensure achievement of contract requirements.
Fair	Ability to control cost issues requires minor customer resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, cost management issues and the Contractor has met the contract requirements.
Excellent	There are no cost management issues and the Contractor has exceeded the contract requirements, achieving cost savings to the customer.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where the contractor achieved cost savings and performance clearly exceeds the performance levels described as "Excellent".

Timeliness of Performance

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Delays are jeopardizing the achievement of contract requirements, despite use of customer resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards.
Poor	Delays require significant customer resources to ensure achievement of contract requirements.
Fair	Delays require minor customer resources to ensure achievement of contract requirements.
Good	There are no, or minimal, delays that impact achievement of contract requirements.
Excellent	There are no delays and the contractor has exceeded the agreed upon time schedule.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Business Relations

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Response to inquiries and/or technical, service, administrative issues is not effective. If not substantially mitigated or corrected it should constitute a significant impediment in considerations for future awards.
Poor	Response to inquiries and/or technical, service, administrative issues is marginally effective.
Fair	Response to inquiries and/or technical, service, administrative issues is somewhat effective.
Good	Response to inquiries and/or technical, service, administrative issues is consistently effective.
Excellent	Response to inquiries and/or technical, service, administrative issues exceeds expectations.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

[END OF SOLICITATION]